Drug Free
AMERICA
Foundation, Inc.

November 3, 2004

Commissioner of the Food and Drug Administration
Docket Management Branch
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Commissioner:

I am writing in reference to Docket 2004P-0472. Fentanyl is used as a surgical anesthetic and may be worn as a transdermal patch. Duragesic, the patch form of the drug, is a powerful narcotic painkiller and is used to treat those who require long-term, continuous medicine delivery. It is just as potent in its generic equivalent form. As a drug policy and prevention expert with more than twenty years in the field, I am urging you to refuse final approval for ANDA 76-258 because of its imminent and unnecessary hazard to public health.

This patch is a time-release medication. To ensure controlled drug delivery, the patch must not be cut or damaged. The Duragesic patch is generally only prescribed when less potent medicines have proved ineffective and pain needs to be controlled 24 hours a day.

This drug is making its way into the hands of drug users and youth. An instance of fentanyl abuse in Florida ended in the tragic overdose and death of 19-year-old Jesse Benedetti. Jesse was not taking it for medical purposes but had obtained it for the purpose of altering his state of mind. He punctured the patch and ingested the time-release medication in one fatal dose. This heartbreaking story could be repeated if others are not made aware of the dangers posed by this new drug being sold illegally to youth.

As the approval for this dangerous substance is being considered, I ask that you please keep in mind that this highly abusable drug will put young people at risk and potentially create a frightening new drug abuse trend.

Sincerely,

Calvina L. Fay
Executive Director

2004P-0472

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